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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,200	06/02/2006	Rasoul Sedaghat Kerdar	512100-2058	3356

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EXAMINER	
LEA, CHRISTOPHER RAYMOND	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
06/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,200	KERDAR ET AL.	
	Examiner	Art Unit	
	Christopher R. Lea	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/EP04/14148.

Receipt of Amendments/Remarks filed on April 15, 2009, is acknowledged. In response to Non-final office action dated December 15, 2009, applicant amended claims 1-7 & 10-12 and added new claims 13 & 14. Claims 1-14 are pending. Claims 1-14 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. All new rejections applied have been necessitated by applicant's amendment to the claims. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

1. The information disclosure statement(s) (IDS) submitted on April 15, 2009, was filed after the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the cellulose ether" in line 1. There is insufficient antecedent basis for this limitation in the claim, as there is not cellulose ether in claim 4 from which claim 14 depends. The examiner will treat claim 14 as thought it reads “The dosage from as claimed in claim 4, characterized in that the hydrophilic polymer is a cellulose ether selected from the group consisting of hydroxyethylcellulose, methylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.”

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupprecht et al. (US PreGrant Publication 2002/0142036) in view of Levin (US Patent 6,432,986).

Applicant claims

Applicant claims a laminar film dosage form containing hydrophilic polymers and lidocaine.

Determination of the scope and content of the prior art (MPEP 2141.01)

Rupprecht et al. teach, as a whole, active agent-containing multi-layer film of hydrophilic polymers.

Claims 1, 2, 4, 6, 7, & 10-12: Rupprecht et al. teach an active agent-containing multi-layer film of film-forming polymers with a cover layer, at least one active substance-containing layer, and an adherent layer (paragraph 2). Rupprecht et al. teach

that the adherent layer is mucoadhesive and the multi-layer film is useful for transmucosal, which includes nasal, administration (paragraphs 47 & 48 and claim 15). Rupprecht et al. teach that the active ingredient-containing layer consists of hydrophilic polymers crosslinked *in situ* (paragraph 8). Rupprecht et al. teach that lidocaine is among the possible active agents which may be incorporable into the multilayer film (paragraph 30). Rupprecht et al. teach the multi-layer film consists of up to 30% active substance based on the overall weight of the film (paragraph 46). This percentage overlaps with the claimed range of 30-60% when one considers that the claimed range is based only on the total weight of the crosslinked polymer, not the overall dosage form. Rupprecht et al. teach that the ratio of polymer to crosslinking agent is 4:1 to 1:1 (paragraph 12).

As to the claimed tear strength, where the claimed and prior art products are substantially identical in composition or produced by a substantially identical process, a *prima facie* case of either obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed tear strength, since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Claims 3, 13, & 14: Rupprecht et al. teach cellulose ethers, particularly hydroxypropyl-methylcellulose as the hydrophilic polymers in the active substance-containing layer (paragraph 20).

Claim 5: Rupprecht et al. teach adding additional polymers to control the release of the active substance (paragraphs 23 & 24).

Claim 8: Rupprecht et al. teach that the active agent diffuses through the adherent layer, so the adherent layer is active ingredient containing. (paragraph 10). Further, Rupprecht et al. teach that (mucoadhesive) polyacrylic acid polymer (which makes the adherent layer adherent) may be added to the active substance-containing layer, which would make allow an active substance-containing layer to be the adhesive layer (paragraph 23).

Claim 9: Rupprecht et al. teach that the covering layer acts as a barrier to prevent diffusion of (i.e., is impermeable to) the active agent (paragraph 10).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Rupprecht et al. and the instant claims is that Rupprecht et al. do not specifically embody the use of lidocaine as the active agent or teach the methods claimed. This deficiency in Rupprecht et al. is cured by the teachings of Levin.

Levin teaches, as a whole, compositions and methods for treating cerebral neurovascular disorders.

Levin teaches that intranasal administration of a composition comprising a sustained release formulation of a shorter-acting local anesthetic treats neurovascular headaches and other related disorders such as migraines (column 16, line 40-51 and column 17, lines 5-13). Levin exemplifies cocaine and lidocaine as shorter-acting local anesthetics (column 13, lines 53-59).

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to select lidocaine from the list of acceptable active agents and incorporate it into the dosage form taught by Rupprecht et al. and produce the instant invention. The skilled artisan would have been motivated to do this because the selection of a known substance based on its suitability for its intended use would have been obvious to the skilled artisan. Further it would have been obvious to select lidocaine from the list based on its known abilities and functions as Levin teaches administering sustained-release lidocaine intranasally for the treatment of migraine headaches; therefore, it would have been obvious to incorporate lidocaine into a dosage form that can be administered nasally, especially one that could offer control of the release profile.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in selecting lidocaine from the list of acceptable active agents and incorporating it into the dosage form taught by Rupprecht et al. and producing the claimed invention. Therefore, the invention as a

whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Response to Arguments

8. Applicant's arguments filed April 15, 2009, have been fully considered but they are not persuasive. Applicant argues that Rupprecht 1) does not teach the ratio of polymer to crosslinker and 2) neither the claimed tear strength nor the conditions required to obtain it. Additionally applicant argues that Rupprecht 3) provide no reason to select lidocaine from the list of acceptable active agents and 4) that there would be not reasonable expectation of success due to the high loading levels claimed.

As to 1) Rupprecht et al. clearly teaches a range for the ratio of polymer to crosslinker (4:1 to 1:2) that overlaps with the claimed range (2:1 to 5:1). As to 2) although the examiner agrees that Rupprecht et al. is silent as to the tear strength, the examiner asserts that the ratio of polymer to crosslinker is the condition required to control the tear strength and as already laid out above, the ratio taught by Rupprecht et al. overlaps with the instantly claimed range. Therefore, the examiner asserts that Rupprecht et al. does, in fact teach the conditions required for the claimed tear strength.

As to 3) Rupprecht et al. specifically teaches lidocaine as a suitable active agent in composition, hence one of ordinary skill in the art would be motivated use it as an active agent (Art Recognized Suitability for an Intended Purpose, MPEP § 2144.07). Further the selection of lidocaine is highly motivated by the teachings of Levin (supra). As to 4) applicant's argument concerning the problem of crystallization with drug loading above 25% is not found convincing. Though the examples of Rupprecht et al. do not approach 25% loading, Rupprecht et al. teach multilayer film compositions containing up to 30% active agent as measured relative to the whole composition, not merely the active-agent-containing layer as claimed in the instant case. When this difference is accounted for, it would obvious to conclude that Rupprecht et al. teaches active-agent-containing layer containing an excess of 30% agent. Applicant's statement concerning "the Rupprecht reference as a whole" is especially odd since applicant's arguments center on the examples taught and not material taught in the specification which was previously pointed out by the examiner.

For all these reasons, the rejection under 35 U.S.C. 103(a) is maintained.

Conclusion

Claims 1-14 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 8:00-4:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616